# COVID-19 Therapeutics Information Brief

March 3, 2022

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Changes to the document from the previous version are highlighted in yellow.

## IMPORTANT/NEW COVID-19 Therapeutics Information



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## Modification to Emergency Use Authorization for AstraZeneca's COVID-19 Evusheld

The U.S. Food and Drug Administration has revised the emergency use authorization for Evusheld (tixagevimab co-packaged with cilgavimab) to change the initial dose for the authorized use as pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric patients.

The modification involves a change to the dosing regimen. **Evusheld now should be administered as an initial dose of 600 mg. Individuals who already received the previously authorized initial 300 mg dose should receive a second Evusheld dose as soon as possible.** Recommendations will be made in the near future when more data are available to determine the appropriate timing of redosing (e.g., a repeat dose with 150 mg of tixagevimab and 150 mg of cilgavimab at 3 months or 6 months after the initial dose).

Based on the most recent information and data available, Evusheld may be less active against certain Omicron subvariants. The dosing regimen was revised because available data indicate that a higher dose

of Evusheld may be more likely to prevent infection by the COVID-19 Omicron subvariants BA.1 and BA.1.1 than the originally authorized Evusheld dose.

**What healthcare professionals should know:**

- Health care professionals should contact patients who received the previously authorized Evusheld dose to return for an additional 150 mg tixagevimab and 150 mg cilgavimab dose as soon as possible.
- The volume of each injection for the new, higher dose will be larger, 3 mL instead of 1.5 mL. This means the injections should be limited to large muscles on the body that can accommodate this volume (e.g., the gluteal muscles).
- Health care professionals should review the updated Fact Sheets and Dear Health Provider Letter for Evusheld.
    - Fact Sheet for Healthcare Providers
    - Healthcare Provider Letter
    - Fact Sheet for Patient's, Parents, and Caregivers
- As part of the EUA, FDA requires health care providers who prescribe Evusheld to report all medication errors and serious adverse events considered to be potentially related to Evusheld through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178.

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## CMS Updates Codes for Bebtelovimab and Remdesivir

CMS released the following new codes for Bebtelovimab and Remdesivir effective February 11, 2022.

**Q0222**

- Long descriptor: Injection, bebtelovimab, 175 mg
- Short descriptor: Bebtelovimab 175

**M0222**

- Long Descriptor: IV injection, bebtelovimab, includes injection and post administration monitoring
- Short Descriptor: Bebtelovimab injection

**M0223**

- Long Descriptor: Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid-19 public health emergency
- Short Descriptor: Bebtelovimab injection home

**Resources**

- CMS COVID-19 Monoclonal Antibodies Toolkit
- Updated FAQs – Payment/Coding for Veklury (Remdesivir) (Pg 146/Question 30)

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## Therapeutic Reporting Reminder and Reporting Wastage Guidance

**Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.**

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **daily** in HPoP. If you need assistance with HPoP, please contact C19therapeutics@idph.iowa.gov.

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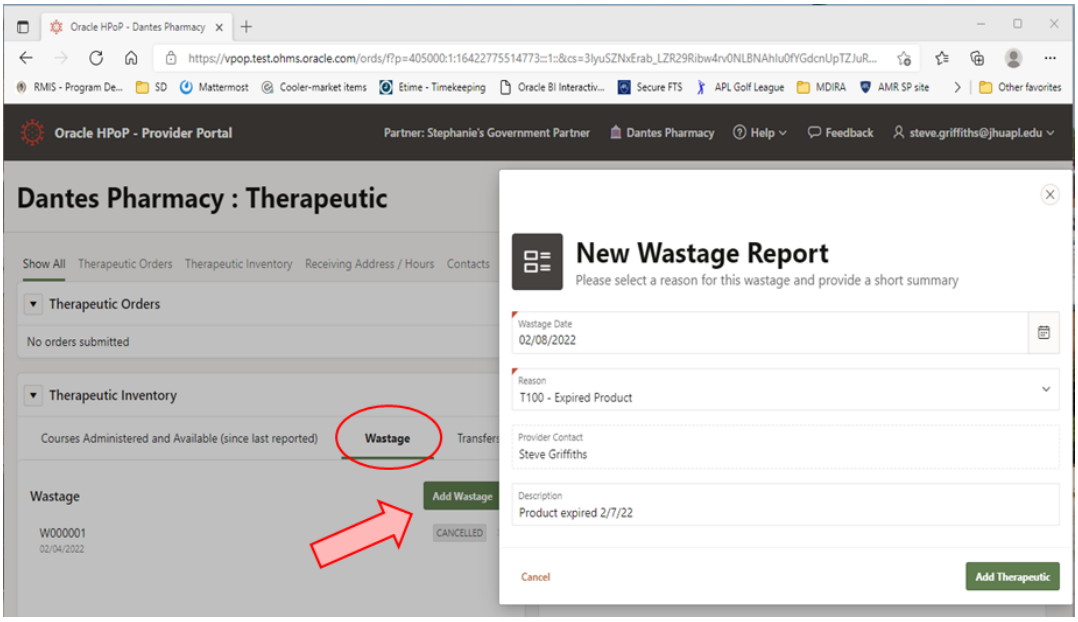
## Reporting Wastage

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green "Add Wastage" button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



## Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

| | Iowa Statewide Allocations for the week<br>Monday, February 28, 2022 - Sunday, March 6, 2022 | | | |
|---|---|---|---|---|
| mAbs | | Oral AVs | | PrEP |
| Bebtelovimab | Sotrovimab | Mulnupiravir | Paxlovid | EVUSHELD |
| **405 courses** | **366 doses** | **0 courses** | **0 courses** | **480 doses** |

Therapeutic product requests from Iowa healthcare providers continue to greatly exceed the number of therapeutic courses allocated to Iowa by the federal government. HHS has clearly stated the intent to decrease the allocation of therapeutics, specifically monoclonals, as Omicron becomes dominant across states. Iowa continues to see a decrease in allocation numbers from the federal government for BAM/ETE and REGEN-COV therapeutics. Please refer to the below talking points to ensure healthcare providers are up-to-date with the current therapeutics allocation process.

- The minimum order quantity for Molupiravir is 24 courses.
- The Iowa Department of Public Health (IDPH) is working to prioritize allocations of therapeutic products based on the regional trends of the variants.
- County by county variant rates *are not* being considered in therapeutic requests due to available data.
- **Allocations will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **Healthcare providers should NOT expect to receive regular (or any) allocations of therapeutic products.**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Therapeutic Information Brief will continue to provide the most up-to-date information regarding the availability of therapeutic products and ordering cadence.
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator. Monoclonals are not well populated yet largely because of availability across the state/nation.
    - The locations displayed in the locator are based on stock on hand as reported by the location and are not a guarantee of availability.
    - Locations that report fewer than 5 courses of the selected therapeutic are not displayed. All therapeutics identified in the locator must be used in alignment with the terms of the respective product's EUA.
    - **This therapeutics locator is intended for provider use, as the included therapies require a prescription by a licensed and authorized provider. Patients should not contact locations directly.**

## Emergency Use Authorization for Eli Lilly's bebtelovimab

The FDA announced emergency use authorization for Eli Lilly's bebtelovimab. Bebtelovimab is a monoclonal antibody product now authorized during this pandemic for the treatment of mild to moderate COVID-19 in adults and certain pediatric patients who are at high risk for progression to severe COVID-19, including hospitalization or death and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

- Bebtelovimab is administered as an intravenous injection.
- The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response will oversee the fair and equitable allocation and distribution of this product.
- Bebtelovimab may only be used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
    - With positive results of direct SARS-CoV-2 viral testing, **and**
    - Who are at high-risk for progression to severe COVID, including hospitalization or death, **and**
    - For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate
- Bebtelovimab usage must be reported in HPoP daily

**Resources:**

- Bebtelovimab EUA Letter of Authorization
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients, Parents and Caregivers
- Frequently Asked Questions for Bebtelovimab

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## Return of bam/ete and REGEN-COV NOT Recommended

Product return of bam/ete and REGEN-COV is ***NOT*** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: https://www.lillytrade.com/
- For REGEN-COV, call 844-734-6643

- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

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## Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGFR

Per Dear HCP Letter endorsed by the FDA, in reference to moderate renal impairment dosing adjusted to 150 mg nirmatrelvir with 100 mg ritonavir taken twice daily for 5 days: "Pharmacists should discard the removed tablets per state requirements or local guidelines." It is recommended providers dispose of the medication via the workflows used to dispose of expired or other waste purposes. The HCP letter and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources.

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## Redistribution Requests for Therapeutics

Requests have been received regarding redistribution of monoclonal antibodies, evusheld and antivirals. Healthcare providers wanting to redistribute antivirals (Paxlovid, Molunpiravir) and pre-exposure prophylaxis (Evusheld) must email the IDPH Therapeutics Call Center at C19Therapeutics@idph.iowa.gov to initiate the redistribution process. **Do not redistribute any doses or courses of antivirals (Paxlovid, Molunpiravir) and pre-exposure prophylaxis (Evusheld) without contacting the Therapeutics Call Center prior to physically transferring.** At this time, monoclonal antibodies do not require IDPH approval for redistribution. Healthcare providers may continue the current practice of monoclonal antibodies redistribution. In the future, monoclonal antibodies may be incorporated into this redistribution policy.

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## Oral COVID-19 Therapeutics Pharmacy Coverage Informational Letter from Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

The link below is to an informational letter updating providers regarding the appropriate billing and coding fees for the use of two oral antivirals for treatment of COVID-19 under an emergency use authorization (EUA).

- Oral COVID-19 Therapeutics Pharmacy Coverage Informational Letter, January 2022

The link below references coverage of over the counter anti-viral information on the HRSA website and correlating FAQs.

- https://www.hrsa.gov/CovidUninsuredClaim
- https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions

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## Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals

Local Public Health Agencies and Hospital Partners should refer to the Iowa Health Alert Network (HAN) Therapeutics folder-partner list for the spreadsheet listing the facilities that have been allocated therapeutics for each type of product.

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## COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
    - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.